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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-08

November 6, 2000

Damon C. Hyde, President
Bryce Clinical Laboratories, Inc.
6340 Benjamin Road, Suite 510
Tampa, Florida 33634

Dear Mr. Hyde:

During an inspection of your testing laboratory on July 18-19 and August 2-11, 2000, our investigator, Joan S. Norton, documented serious violations of Section 361(a) of the Public Health Service Act [42 U.S.C. 264(a)].

The inspection revealed significant deviations from the donor screening, testing, and written procedure requirements specified in the regulations for Human Tissue Intended for Transplantation [Title 21, Code of Federal Regulations, Parts 1270.21(a) and 1270.31(a)] as follows:

Eye bank and/or tissue bank donor samples received by your laboratory are not being tested for HBsAg in accordance with the test kit manufacturer's instructions.

Your established written procedures for HBsAg, HIV 1-2 and HCV testing do not conform to the test kit manufacturer's directions. For example, your written procedures fail to specify that all initially reactive samples are to be retested in duplicate, fail to specify the amount of sulfuric acid added to stop reactions, and fail to include procedures for interpretation of test results.

There was no documentation available to show that a single donor sample 1093445/6 was ever tested for HBsAg. However, a final negative test result was reported to the client.

Five donor samples (1093805, 1094020, 1094495, 1095384 and 1095865) tested initially reactive for HBsAg between June 9 and July 14, 2000. Repeat testing was not performed in duplicate and negative test results were reported to the client. A technician admitted diluting at least three of these samples and/or controls with acid and reporting the results as negative based on single repeat tests and/or re-reading the sample absorbencies.

At least five more donor samples (1085751, 1086149, 1091992, 1092474 and 1092883) tested initially reactive for HBsAg between January 7 and May 24, 2000. Repeat testing was not performed in duplicate and negative test results were reported to the client based on subsequent negative HBsAg neutralization tests. At the conclusion of the inspection, you informed the investigator that at least eleven more donor samples were tested in this same manner. Negative test results were also reported to the client for these eleven samples.

There was no documentation available to explain why a technician was re-reading absorbencies and handwriting sample numbers on the test strip for an HBsAg batch run on June 26, 2000. The absorbencies for six samples (1094379, 1094741, 1094742, 1094743, 1094744 and 1094745) were above the cutoff and negative test results were reported to the client. A subsequent retest in duplicate of a reserve specimen for sample 1094743 on August 3, 2000 tested repeatedly reactive.

Viral marker batch test records maintained by your firm fail to identify the test kit lot number, date of testing, and do not identify the technician performing the test.

The violations identified above are not intended to be an all-inclusive list of deficiencies at your laboratory. It is your responsibility to ensure that all viral marker testing to determine the suitability of human tissue for transplant is performed in compliance with the Public Health Service Act and with the requirements of the tissue regulations. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice.

We request that you notify this office in writing within 15 working days from your receipt of this letter. Your response should outline the specific steps you have taken to correct these violations, including steps being taken to prevent the recurrence of similar violations. You may wish to include in your response documentation such as reserve sample test records, revised written procedures, training records, client notifications or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when these violations will be corrected.

Please send your reply to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District